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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/899,276 | 07/06/2001 | Frank Roesl | 012627-023 | 3914 |

21839 7590 08/09/2005

BUCHANAN INGERSOLL PC
(INCLUDING BURNS, DOANE, SWECKER & MATHIS)
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| EXAMINER | |
|---|---|
| ANGELL, JON E | |
| **ART UNIT** | **PAPER NUMBER** |
| 1635 | |

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/899,276 | ROESL ET AL. | |
| | Examiner | Art Unit | |
| | Jon Eric Angell | 1635 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *7-10,16,18,19 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10,16,18,19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *attachment*.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/23/2005 has been entered.

The amendment filed 5/23/2005 is acknowledged. The amendment has been entered. Claims 1-6, 11-15, 17 and 20 have been cancelled. New claim 21 has been added. Claims 7-10 16, 18, 19 and 21 are currently pending in the application and are addressed herein.

It is noted that claims 11-15 have been cancelled, however, the text of claims 11-15 is presented in the current claims listing. Applicants are referred to 37 CFR 1.121(c)(4)(i) which states, "No text shall be presented for any claim in the claim listing with the status of 'cancelled' or 'not entered'." In the interest of compact prosecution, claims 11-15 are considered cancelled and claims 7-10, 16, 18, 19 and 21 are examined herein.

### *Priority*

Acknowledgment is made of applicant's claim for foreign priority based on European Patent Application No. 00114560.6, filed on July 6, 2000. It is noted, however, that although a communication filed by Applicants on 10/30/2001 indicates that a certified copy of European Patent Application No. 00114560.6 has been submitted, the certified copy is not present in the

scanned file. Therefore applicant's must submit a certified copy of the application as required by 35 U.S.C. 119(b).

***Claim Objections***

Claim 16 is objected to because of the following informalities: claim 16 comprises the phrase, "a nucleic acid which hybridize to the nucleotide sequence of SEQ ID NO: 13" (emphasis added for clarity). It appears that the word "hybridize" is a typographical error and should be "hybridizes".

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-10, 16, 18 and 19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It is noted that claim 16 has been amended. However, amended claim 16 encompasses an isolated nucleic acid comprising a nucleic acid sequence encoding MCP-1, including "allelic variants" of MCP-1, sequences which are "degenerate as a result of the genetic code to SEQ ID NO: 13", and nucleic acid sequences which hybridize to SEQ ID NO: 13 under stringent conditions.

Therefore, the claims are drawn to a genus of molecules (i.e., nucleic acids) wherein the molecules encompass nucleic acid sequences that are different from the sequence encoding MCP-1, including allelic variants degenerate sequences of SEQ ID NO: 13 as well as all nucleic acid sequences which would hybridize to SEQ ID NO: 13 under stringent conditions. It is noted that the specification defines the term "allelic variant" by stating, "The allelic variants can either be naturally occurring variants or synthetically produces variants or variants produced by recombinant DNA processes" (see page 5, lines 1-5 of the specification). Therefore, the "allelic variants" encompassed by the claims include naturally occurring variants as well as synthetic variants. Given the broadest reasonable interpretation, the variants encompassed by the claims include synthetic variants wherein any nucleotide or nucleotides of the sequence are changed. It is noted that amended claim 16 does not explicitly indicate that the isolated nucleic acid molecule encodes a sequence that has MCP-1 activity. Therefore, the claims encompass sequences which encode polypeptides that do not have MCP-1 including sequences which have a different function as well as non-functional variants. This genus of molecules encompasses possibly thousands or millions of different molecules, considering every possible sequence encompassed by the claims. Furthermore, it is noted that the specification (as well as the prior art) does not disclose the critical elements of MCP-1 such that one of skill in the art would know which variants would have MCP-1 biological activity and which variant would not have MCP-1 biological activity, without performing additional experimentation.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or

chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is that the sequence encodes an allelic variant MCP-1. There is no identification of any particular portion of the sequence that must be conserved among all species members. Since the specification and prior art do not describe the features of human MCP-1 which are critical to the functional activity of MCP-1 polypeptide, there is no known structure–function relationship for the molecules encompassed by the claims. It is noted that a review of the prior art identified that there are at least two sequence homologues of human MCP-1, one encoding mouse JE and another encoding human JE (e.g., see Rollins et al., MCB 1998; previously cited); however, the sequence structures of these homologues which are critical to conferring the biological activity of MCP-1 to the proteins are not described. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). Here, the skilled artisan cannot envision the detailed chemical structure of the genus of molecules encompassed by the claims, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the

invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Therefore, only isolated nucleic acids encoding the amino acid sequence encoded by SEQ ID NO: 13 meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

It is noted that claims 7-10, 18 and 19 are dependent claims that depend on either claim 16. The dependent claims encompass all of the limitations of the independent claims; therefore, claims 7-10, 18 and 19 are rejected for the same reason.

Claims 7-10, 16, 18 and 19 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

> An isolated nucleic acid molecule comprising: (a) a nucleic acid sequence encoding MCP-1, wherein the MCP-1 protein is the protein encoded by SEQ ID NO: 13; and (b) a 5'-DHSR or 3'-DHSR wherein said 5'DHSR contains the nucleic acid sequence that is SEQ ID NO: 4, 5, or 6 and wherein said 3'-DHSR comprises the nucleic acid sequence that is TGAGTCA, or SEQ ID NO: 1, 2, 3, or 8;
>
> As well as a recombinant vector comprising said isolated nucleic acid molecule and an **isolated recombinant host cell** which contains said isolated nucleic acid molecule;

does not reasonably provide enablement for nucleic acid molecules which encode MCP-1 variants which do not have MCP-1 biological activity or a non-isolated host cells comprising said nucleic acid molecule. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 8 USPQ2d 1400 (CA FC 1988).

*Wands* states on page 1404,

> "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The invention is in a class of invention which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v. Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The instant claims are drawn to isolated nucleic acid molecules which encode MCP-1 variants which include variants that are structurally and functionally different from the disclosed MCP-1 protein. Furthermore, claims 9 and 10 encompass a recombinant host cell which contains a nucleic acid molecule according to claim 16 (claim 9), wherein the recombinant cell can be a mammalian, bacterial, insect or yeast cell (claim 10). Given the broadest reasonable interpretation the claims encompass a recombinant cell in a transgenic mammal or insect.

With respect to the variant nucleic acid molecules encompassed by the claims, it is noted that the claims encompass a very large genus of structurally and functionally different molecules as indicated above. In fact, the claims encompass nucleic acid molecules which encode polypeptides that do not have MCP-1 function (monocyte chemoattraction), including proteins which are non-functional. One of skill in the art would not know how to use a protein having a

function other than MCP-1 function without performing additional experimentation to identify the function and a use for the variants which do not have monocyte chemoattracting function. Considering the vast number of different species molecules encompassed by the claims, the amount of additional experimentation required to make the variants and identify their function is considered undue.

With respect to making transgenic animals, it is noted that the prior art recognizes that making such genetically modified animals is unpredictable. For instance, the relevant art has for many years stated that the unpredictability of making transgenic animals lies with the site or sites of integration of the transgene into the target genome. Transgenic animals are regarded to have within their cells mechanisms which prevent expression of the transgene, such as DNA methylation or deletion from the genome (**Kappel et al.** (1992) Current Opinion in Biotechnology, Vol. 3, p. 549, col. 2, parag. 2). Furthermore, **Mullins et al.** states that not all animals express a transgene sufficiently expresses the transgene as the integration of a transgene into difference species of animal has been reported to given divergent phenotypes (**Mullins et al.** (1993) Hypertension Vol. 22, page 631, col. 1, parag. 1, lines 14-17). Also, **Mullins et al.** (1996) teaches that "the use of nonmurine species for transgenesis will continue to reflect the suitability of a particular species for the specific questions being addressed, bearing in mind that a given construct may react very differently from one species to another." (**Mullins et al.** (1996) J. Clin. Invest. Vol. 97, page 1559, Summary). Furthermore, well-regulated expression of the transgene is not frequently achieved because of poor levels or the complete absence of expression or leaky expression in non-target tissues (**Cameron** (1997) Molec. Biol. Vol. 7, page 256, col. 1 -2, bridg. parag.). Factors influencing low expression, or the lack thereof, are not

affected by copy number and such effects are seen in lines of transgenic mice made with the same construct (**Cameron** (1997), page 256, lines 3-9). These factors, thus, are copy number independent and integration site dependent, emphasizing the role the integration site plays on expression of the transgene (**Cameron** (1997), page 256, lines 10-13).

While, the intent is not to say that genetically modified animals can never be made, the intent is to provide art taught reasoning as to why the instant claims are not enabled to their full scope. Given such species differences in the expression of a transgene, particularly when taken with the lack of guidance in the specification, it would have required undue experimentation to predict the results achieved in any engineered mammal comprising the claimed cell(s).

Considering the nature of the invention, the breadth of the claims, the unpredictable nature of the invention as recognized in the prior art, the limited amount of working examples and guidance provided, and the high degree of skill required to practice the invention, it is concluded that the specification does not provide an enabling disclosure for the full scope of the instant claims. Therefore, additional experimentation is required before one of skill in the art could make and use the claimed invention to the full scope encompassed by the claims. The amount of additional experimentation required to make and use the broadly claimed invention is undue.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-10, 16, 18, 19 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Birren et al. (Genbank Accession No. AC005549; cited by Applicants on the IDS PTO-1449 filed 10/30/2001).

The instant claims are drawn to an isolated nucleic acid molecule "consisting essentially of": (a) a nucleic acid sequence encoding MCP-1, the protein encoded by SEQ ID NO: 13, or an allelic variant thereof or a nucleic acid sequence which hybridizes to the nucleotide sequence of SEQ ID NO: 13 under stringent conditions; and (b) at least one hypersensitive region selected from the group consisting of SEQ ID NOS: 1-6, 8 or TGATCA.

Regarding the limitation "consisting essentially of" it is noted that MPEP 2111.03 states:

"The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original)... For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, 'consisting essentially of' will be construed as equivalent to 'comprising' See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that 'silicon contents in the coating metal should not exceed about 0.5% by weight' along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, 'consisting essentially of' as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention."

Therefore, in the instant case, the claims encompass a nucleic acid comprising (a) and (b), as indicated above, as well as anything else that does not materially affect the basic and novel characteristics of the claimed nucleic acid.

Birren (Genbank Accession No. AC005549) teaches a bacterial artificial chromosome (BAC) comprising a 147 kb fragment of chromosome 17 which includes SEQ ID NO. 1 as well as a DNA sequence encoding the human MCP-1 gene (SEQ ID NO: 13). The Genbank data indicates that the sequence is comprised in a recombinant BAC vector (hRPK.215_E_13), which includes the genomic sequence encoding human MCP-1 (SEQ ID NO: 13), as well as more than 130kb of human chromosome 17 sequence. Since the sequence taught by Birren is a fragment of human chromosome 17, the sequence taught by Birren which is not SEQ ID NO: 13 or the indicated DHSRs is not considered to materially effect the basic and novel characteristics of the claimed invention.

Since Birren teaches an isolated nucleic acid sequence having SEQ ID NO. 1 (the 3'DHSR nucleic acid sequence comprising nucleotides from position +2430 to +3019 as depicted in Figure 6) and SEQ ID NO: 13 (human MCP-1), as well as 130kb sequence of human chromosome 17, Birren teaches an isolated nucleic acid sequence comprising (a) and (b), as indicated above, which would necessarily comprise the regulatory elements of the MCP-1 gene operatively linked to the human MCP-1 gene which would allow transcription and synthesis of a translatable RNA in eukaryotic cell. Furthermore, since the additional sequence taught by Birren would not materially effect the basic and novel characteristics of the claimed sequence, the BAC taught by Birren in Genbank Accession No. AC005549 meets the limitations of claim 16.

It is noted that the BAC taught by Birren is a recombinant vector that includes a 147 kilobase part of chromosome 17, which includes the 11kb sequence of SEQ ID NO: 13 (human MCP-1) and which would necessarily include the regulatory sequences associated with the expression of MCP-1 in human cells including the 5'-DHSRs, the 3'-DHSRs as well the MCP-1 promoter sequences associated with the MCP-1 gene. Furthermore, the construction of the BAC would necessarily require the transformation of the BAC into bacterial cells for the propagation of the instant BAC. As such, Birren (through Genbank Accession No. AC005549) necessarily teaches all of the limitations of the instant claims.

***Response to Arguments***

Applicant's arguments filed 5/23/2005 have been fully considered but they are not persuasive.

With respect to the rejection of claims under 35 USC 112, 1st paragraph, Applicants argue that the MCP-1 protein itself was known and that the skilled artisan could determine the allelic variants, degenerate sequences and other allelic mutants through hybridization performed under stringent conditions (see pages 7-8 of the response filed 5/23/2005). Applicants also contend that the claim has been amended to remove recitation of fragments, derivatives and variant sequences (page 8 of the response).

In response, it is noted that the claim explicitly encompasses allelic variants and degenerate sequences. Considering that the specification indicates that "allelic variants" encompasses naturally occurring variants, synthetically produced variants and variants produced by recombinant DNA processes, and given the broadest reasonable interpretation, "allelic

variant" encompasses any synthetically produced variant of MCP-1. Therefore, the claims encompass a genus comprising a number of different species, as indicated above. Furthermore, regarding Applicants' argument that one of skill in the art could determine the variants encompassed by the claim by performing additional experimentation, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it, the compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Applicants are also reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Furthermore, although the claims have been amended such that the no longer encompass DHSR variants it is noted that the claims encompass MCP-1 variants including variants that do not have monocyte chemoattracting function. Furthermore, the claims also encompass non-isolated recombinant host cells. The specification does not provide an enabling disclosure for making and using the genus of MCP-1 variants or non-isolated host cells encompassed by the claims for the reasons indicated above.

Therefore, Applicants arguments are not persuasive and the rejection is not withdrawn.

With respect to the rejection of claims under 35 USC 102, Applicants argue that claim 16 has been amended such that it is limited to an isolated nucleic acid molecule consisting essentially of: (a) a nucleic acid sequence encoding MCP-1, the protein encoded by SEQ ID NO: 13, or an allelic variant thereof or a nucleic acid sequence which hybridizes to the nucleotide sequence of SEQ ID NO: 13 under stringent conditions; and (b) at least one hypersensitive

region selected from the group consisting of SEQ ID NOS: 1-6, 8 or TGATCA. Applicants contend that Birren does not even suggest the defined hypersensitive regions recited in claim 16 and does not provide sufficient guidance to reproduce the claimed nucleic acid molecule (see page 10). Therefore, Applicants assert that Birren is not enabled and thus cannot anticipate the claimed nucleic acid.

In response, it is acknowledged that claim 16 has been amended to include the recitation "consisting essentially of". However, as indicated above, MPEP 2111.03 states:

> "The transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original)... If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention."

In the instant case Birren does teach each and every element of the claimed nucleic acid sequence. Specifically, Birren teaches EMBL Accession No. Y18933 which is SEQ ID NO: 13, as acknowledged in by Applicants (e.g., see page 6-7 of Applicants response filed 5/23/2005 as well as page 3 of the specification). Therefore, the nucleic acid taught by Birren (EMBL Accession No. Y18933, SEQ ID NO: 13) comprises a nucleic acid sequence that encodes MCP-1 polypeptide. Furthermore, the sequence taught by Birren further comprises a nucleic acid sequence that is 100% identical to SEQ ID NO: 1 (a 3'-DHSR, as indicated in claims 16(b); see attached sequence alignment of SEQ ID NO: 1 and EMBL Accession No. Y18933). Therefore, Birren teaches a sequence encoding MCP-1 protein as well and further comprising the DHSR sequence that is SEQ ID NO: 1. It is noted that Birren teaches a nucleic acid sequence comprising a fragment of human chromosome 17. As such, the nucleic acid

sequence of Birren would also comprise any regulatory sequences of the MCP-1 gene, including SEQ ID NOS: 1-6, 8 and the sequence TGATCA. Therefore, Birren teaches a sequence having all of the structural limitations of the claimed nucleic acid sequence. Furthermore, the additional sequence taught by Birren (i.e., the sequence that is not the MCP-1 gene and regulatory sequences) would not materially affect the basic and novel characteristics of the claimed nucleic acid sequence, as the sequence of Birren comprises the MCP-1 gene and regulatory sequences as it is found in chromosome 17. Furthermore, it is respectfully pointed out that the claims are drawn to an isolated nucleic acid sequence (a product) and that Birren teaches an isolated nucleic acid sequence which meets all of the structural elements of the claims. Since the product has all of the sequence requirements of the claim, the product must, by necessity, have all of the functional properties as well. Therefore, Birren does provide an enabling disclosure for the disclosed nucleic acid sequence.

Applicants are reminded that MPEP 2112.01 indicates, "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). 'When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.'"

Here, the Office has shown a sound basis for believing that the products of the claim and the product of Birren are the same. Therefore, the rejection of claims is proper and the rejection is not withdrawn.

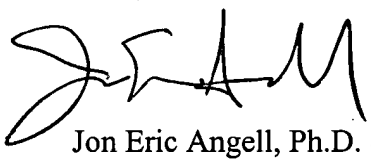
***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jon Eric Angell, Ph.D.
Art Unit 1635

Attachment

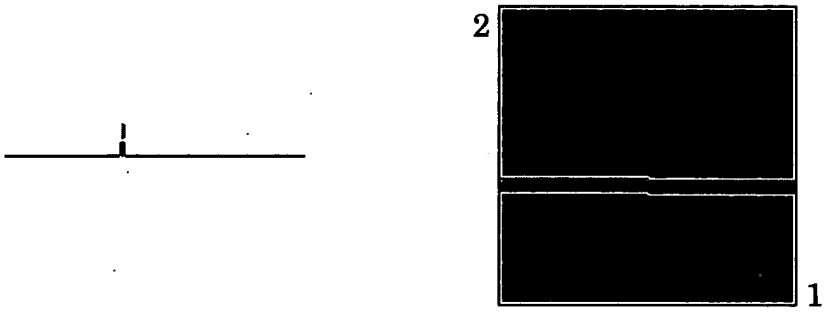
# Blast 2 Sequences results

PubMed Entrez BLAST OMIM Taxonomy Structure

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.10 [Oct-19-2004]

Match: 1 Mismatch: -2 gap open: 5 gap extension: 2
x_dropoff: 50 expect: 10.000 wordsize: 11 Filter ☑ Align

| | | | |
|---|---|---|---|
| **Sequence 1** | lcl\|seq_1 | **Length** 600 | (1 .. 600) |
| **Sequence 2** | gi 3598724 | Homo sapiens chromosome 17, clone hRPK.215_E_13 | **Length** 147416 (1 .. 147416) |




NOTE:The statistics (bitscore and expect value) is calculated based on the size of nr database

NOTE:If protein translation is reversed, please repeat the search with reverse strand of the query sequence

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Score = 1154 bits (600), Expect = 0.0
Identities = 600/600 (100%)
 Strand = Plus / Minus
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Query: 1     taggaaaattataggatcattaagaaaggagaaggaagagtgggagcaaatacctggagg 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 59034 taggaaaattataggatcattaagaaaggagaaggaagagtgggagcaaatacctggagg 58975


Query: 61    tagaaatggtgatgatgtgtacatcaagcagggagaaaaccaatgaaccagatgcgaatt 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58974 tagaaatggtgatgatgtgtacatcaagcagggagaaaaccaatgaaccagatgcgaatt 58915


Query: 121   cgggcccacaccaatgtcaagggatgacaattagaaaggaaggttgagtcaagggatttg 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58914 cgggcccacaccaatgtcaagggatgacaattagaaaggaaggttgagtcaagggatttg 58855


Query: 181   aatgttagggtgaaaagttactactcaactctgtaggttaaaaggaaacgttgagaatct 240
```

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            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58854 aatgttagggtgaaaagttactactcaactctgtaggttaaaaggaaacgttgagaatct 58795


Query: 241   tcagtccaatgaggagggatgtgccatgtttagagattcagagataagtttcaggaaatg 300
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58794 tcagtccaatgaggagggatgtgccatgtttagagattcagagataagtttcaggaaatg 58735


Query: 301   taacttatagattttatacatacacagagaaatacggactagtgagaagctattgccatg 360
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58734 taacttatagattttatacatacacagagaaatacggactagtgagaagctattgccatg 58675


Query: 361   gtccaagcaagagatgatgaaggcctaaatatggagccaaagaggcagcaatgaagaatg 420
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58674 gtccaagcaagagatgatgaaggcctaaatatggagccaaagaggcagcaatgaagaatg 58615


Query: 421   agccatgcagggtgaaatgctgcatgttgtaaatggaggagaaagacctgtgacttcaga 480
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58614 agccatgcagggtgaaatgctgcatgttgtaaatggaggagaaagacctgtgacttcaga 58555


Query: 481   tatgaaaacctcatcttcaacccacattttaaggggcagcttccctgaaaccagaatgt 540
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58554 tatgaaaacctcatcttcaacccacattttaaggggcagcttccctgaaaccagaatgt 58495


Query: 541   gtttccctccattactatacccccatcccaatctcaggcacctggaatcatccatttaaa 600
            ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 58494 gtttccctccattactatacccccatcccaatctcaggcacctggaatcatccatttaaa 58435

CPU time:     0.03 user secs.       0.01 sys. secs          0.04 total secs.

Lambda     K      H
    1.33    0.621     1.12

Gapped
Lambda     K      H
    1.33    0.621     1.12


Matrix: blastn matrix:1 -2
Gap Penalties: Existence: 5, Extension: 2
Number of Sequences: 1
Number of Hits to DB: 1412
Number of extensions: 78
Number of successful extensions: 1
Number of sequences better than 10.0: 1
Number of HSP's better than 10.0 without gapping: 1
Number of HSP's gapped: 1
Number of HSP's successfully gapped: 1
Number of extra gapped extensions for HSPs above 10.0: 0
Length of query: 600
Length of database: 14,848,724,355
Length adjustment: 26
Effective length of query: 574
Effective length of database: 14,848,724,329
Effective search space: 8523167764846
```

```
Effective search space used: 8523167764846
Neighboring words threshold: 0
Window for multiple hits: 0
X1: 11 (21.1 bits)
X2: 26 (50.0 bits)
X3: 26 (50.0 bits)
S1: 17 (33.4 bits)
S2: 21 (41.1 bits)
```